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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,462	10/07/2003	Dwight H. Warkentin	P-11548.00	5179
27581	7590	02/22/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			SMITH, TERRI L	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 02/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

10/680,462

Applicant(s)

WARKENTIN ET AL.

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-24-04</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 24 May 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the Examiner. However, the Examiner notes that U.S. Patent Application Number 2003/0020364 and U.S. Patent 6,126,526 listed on the IDS do not appear to be germane to the subject matter of this patent application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “means for vibrating the implantable device” (claim 22) and the “means for displaying an indicia” (claim 23) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are further objected to because Fig. 5 has a typographical error in box 625. It appears that “Pulst” should be “pulse” instead.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: On page 4, in lines 3–6, the portion of the sentence “of while avoiding the risk of arrhythmia, particularly during ischemic episodes” is unclear.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In independent claims 4, 11, and 18, the limitation “a volume of myocardial tissue” is not disclosed in the specification.

In claims 9, 15, and 22, the limitation “vibrating the implantable pulse generator” is not expressly, implicitly, or inherently disclosed in the specification.

In claims 10, 16, and 23, the limitations “displaying an indicia by or on the remote device” and “a visual indicia” are not expressly, implicitly, or inherently disclosed in the specification.

Appropriate correction is required.

Claim Objections

5. Claims 2–3, 5–10, 12–17, and 19–24 are objected to because of the following informalities: It is customary in claim language that after a limitation is introduced by the word

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“a” the next mention of the limitation is preceded by either the word “the” or “said” as a clear indicator that the limitation has been introduced. It is suggested that in each of the claims objected to the first word in each claim be changed from the word “a” to the word “the.” Additionally, in claim 4, it appears that the word “monitors” should be the word “monitor” instead.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 3 and 11–17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11, the phrase “a computer readable medium ... performing a method” is vague and indefinite. It is unclear if the Applicant is claiming an article of manufacture (a computer readable medium) or a process (performing a method). As a result of the vagueness of claim 11, all of the dependent claims (12–17) are equally unclear as they refer to a method and it is unclear what the Applicant is claiming in the independent claim (17) from which these claims depend.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1–4, 6–11, 13–18, and 20–24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness, U.S. Patent 5,531,768, and in view of Heinze et al., U.S. Patent 6,920,353.

11. Regarding claim 1, Alferness discloses detecting myocardial ischemia (Figs. 1–2; column 4, line 59–column 5, lines 1–6); and responding to a myocardial ischemia detection by modifying a delivery of stimulation therapy (column 2, lines 37–45), but not ESS therapy. However, Heinze discloses ESS therapy (Figs. 3 and 1; column 6, lines 10–24; column 3, lines 41–43; column 4, lines 4–30) to render a quick and accurate regulation of therapy and to avoid too high a stimulation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Alferness to include ESS therapy to provide prompt and accurate therapy to the patient.

Alferness discloses modifying delivery of stimulation comprises any of: disabling stimulation therapy delivery; initiating stimulation therapy delivery; modifying at least one stimulation therapy delivery control parameter (claim 2) (Fig. 2; column 2, lines 4–19), but not ESS. However, Heinze discloses modifying delivery of ESS comprises any of: disabling ESS

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therapy delivery; initiating ESS therapy delivery; modifying at least one ESS therapy delivery control parameter (column 6, lines 10–24) to render a quick and accurate regulation of therapy and to avoid too high a stimulation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Alferness to include modifying delivery of ESS comprises any of: disabling ESS therapy delivery; initiating ESS therapy delivery; modifying at least one ESS therapy delivery control parameter to provide prompt and accurate therapy to the patient.

Alferness discloses detecting an absence of myocardial ischemia subsequent to an initial affirmative ischemia detection; and modifying stimulation therapy delivery (claim 3) (Fig. 5; column 2, lines 42–44), but not ESS therapy. However, Heinze discloses ESS therapy for the same reasons and motivation as disclosed in paragraph 13 above. (**NOTE:** In the interest of brevity, Examiner is making this reference rather than repeating it for a third time. Additionally, Heinze will be cited for every ESS therapy limitation set forth in the claimed invention throughout the remainder of this Office Action for the same reasons and motivation as disclosed in paragraph 11 above without repeating the language).

With respect to claims 4, 11, and 18, Alferness discloses monitoring a volume of myocardial tissue for a myocardial ischemic condition and providing an output signal related to a presence or an absence of a myocardial ischemia condition (Alferness column 4, line 59–column 5, lines 1–6); in the event that an output signal indicates the presence of a myocardial ischemic condition and a stimulation therapy is presently being applied to a volume of myocardial tissue, at least temporarily ceasing further delivery of a stimulation therapy (column 1, lines 13–15;

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column 5, lines 35–42); and in the event that the output signal indicates the presence of the myocardial ischemic condition and the stimulation therapy is not presently being applied to the volume of myocardial tissue, initiating delivery of the stimulation therapy (column 7, lines 37–44; column 1, lines 50–54 and 58–64, this reference supporting atrial fibrillation as a cause of myocardial ischemia). Alferness does not disclose ESS therapy. However, Heinze discloses ESS therapy as disclosed in paragraph 11 above.

Alferness discloses a monitoring step further comprises: determining a variation in: a cardiac conduction interval from pacing pulse delivery to resultant depolarization over at least two different cardiac cycles, a present sensor signal output compared to a prior sensor signal output, wherein a sensor couples to a portion of myocardial tissue and comprises one of: a mechanical sensor, a biological sensor, a metabolic sensor; a variation in S-T segment parameters relative to an isoelectric baseline parameter (column 5, lines 8–18), or a variation in a portion of a T-wave of a PQRS complex, using a cardiac electrogram signal vector for determining the onset, presence or absence of an ischemia condition (claims 6, 13, and 20); a cardiac electrogram vector comprises at least a one of: a tip-to-ring electrode vector (Fig. 1, elements 38 and 40), a coil-to-can electrode vector (Fig. 2; paragraph [0032], lines 5–7), a coil-to-coil electrode vector, a tip-to-can electrode vector, a ring-to-can electrode vector, a ring-to-ring vector (claims 7, 14, and 21); a method is performed on a computer readable medium disposed within an implantable pulse generator (claim 8) (Fig. 1); wirelessly transmitting an output signal to a remote device (Fig. 1 2); and/or vibrating the implantable pulse generator in relation to a state change in the output signal (claims 9, 15, and 22); displaying an indicia by or on a remote device, wherein the indicia comprises a visual indicia related to an output signal

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(claims 10, 16, and 23) (Fig. 1; column 6, lines 13–17); a remote device is capable of being coupled to a clinician information network (claims 17 and 24) (Fig. 1).

12. Claims 5, 12, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness, U.S. Patent 5,531,768 and Heinze et al. as applied to claims 4, 11, and 18 above, and further in view of Lu, Patent Application Publication U.S. 2002/072777.

Alferness and Heinze do not disclose in the event that an output signal indicates the absence of the myocardial ischemic condition and a stimulation therapy is presently being applied to the volume of myocardial tissue, then either: continuing delivery of the ESS therapy, or mode-switching to another cardiac stimulation therapy modality. However, Lu discloses in the event that an output signal indicates the absence of the myocardial ischemic condition and a stimulation therapy is presently being applied to the volume of myocardial tissue, then either: continuing delivery of a stimulation therapy, or mode-switching to another cardiac stimulation therapy modality (Fig. 3A, the portion represented by reference character 121). Lu does not disclose ESS therapy. However, Heinze discloses ESS therapy as disclosed in paragraph 14 above, except changing "... the invention of Alferness ..." to "... the modified inventions of Alferness and Lu ..." in the motivation statement.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

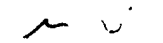
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



TLS

February 17, 2006

17 February 2006



GEORGE R. EVANISKO
PRIMARY EXAMINER

2/17/06